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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/728,992	12/08/2003	John Hefti	262.4	1110
7590	04/15/2005		EXAMINER	
Joseph Page P.O. Box 757 La Jolla, CA 92038			KREMER, MATTHEW J	
			ART UNIT	PAPER NUMBER
			3736	
DATE MAILED: 04/15/2005				

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/728,992

Applicant(s)

HEFTI ET AL.

Examiner

Matthew J Kremer

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-28 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-28 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. ____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date ____.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: ____.

DETAILED ACTION

Specification

1. The specification is objected to as failing to provide proper antecedent basis for the claimed subject matter. See 37 CFR 1.75(d)(1) and MPEP § 608.01(o). Correction of the following is required: claim 14 claims that "said pulses are formed into sets of pulses, or a pulse stream, of finite length, said sets of pulses being characterized as having a duty cycle less than 1/4" but there is no particular teaching in the specification of this upper limit.

Claim Rejections - 35 USC § 101

2. 35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title:

3. Claims 1-21 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. Claim 1 recites the limitation "the optical source being coupled to a tissue test site" which improperly includes the human body as part of the claimed invention. Claim 10 recites the limitation "said pressure transducer is coupled to the tissue test site via a coupling whereby the pressure transducer makes intimate and direct contact with a tissue surface" which improperly includes the human body as part of the claimed invention. Claim 11 recites the limitation "said pressure transducer is coupled to said tissue test site via a coupling comprised of a fluid operable

for transmitting an acoustic wave therethrough.” which improperly includes the human body as part of the claimed invention.

Claim Rejections - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

5. Claims 1-5, 12, 16-18, 22-23, and 27-28 are rejected under 35 U.S.C. 102(b) as being anticipated by U.S. Patent 6,484,044 to Lilienfeld-Toal. (Lilienfeld-Toal).

Lilienfeld-Toal teaches the use of an optical source in the form of a semiconductor laser that permits transmission of mid-infrared laser light and the use of a pressure transducer system in the form of a photoacoustic detector. (Abstract of Lilienfeld-Toal).

In regard to claim 2, a photoacoustic effect is detected for determining a substance in a sample. (Abstract of Lilienfeld-Toal). In regard to claim 3, quantum well structures are disclosed. (column 2, lines 57-58 of Lilienfeld-Toal). In regard to claims 4-5, a plurality of lasers is disclosed. (column 4, lines 20-24 of Lilienfeld-Toal). In regard to claims 12, 23, and 25-26, the use of a modulation system is disclosed in the form of microprocessor 8. (column 3, lines 34-38 and column 4, lines 17-20 of Lilienfeld-Toal). In regard to claims 16-17, wavelengths are selected at peaks and valleys of the absorption spectrum. (column 4, lines 3-6 and Fig. 3 of Lilienfeld-Toal). In regard to

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claim 18, Fig. 3 shows the various wavelengths include: 1151, 1105, 1080, 1036, 992, 1181, 1140, 1094, 1066 and 1014 cm^{-1} . (Fig. 3 and column 4, lines 7-24 of Lilienfeld-Toal). In regard to claim 27, the tissue, which includes the interstitial fluid, is illuminated. (Abstract of Lilienfeld-Toal). In regard to claim 28, the laser beam penetrates the skin and into underlying tissue, which inherently means that penetration depth is at least 200 microns since the dermis is typically 200-500 microns deep.

Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

7. Claims 1-7, 9-15, 19-20, and 22-28 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent 5,348,002 to Caro in view of U.S. Patent 6,148,012 to Capasso et al. (Capasso). Caro discloses a method and apparatus for determining the presence and/or concentration of chemical species, which includes electromagnetic energy being absorbed by tissue. The absorbed electromagnetic energy generates acoustic energy, which is detected and analyzed (Abstract of Caro). The radiation source can be one or more diode lasers (column 11, lines 4-11 of Caro). Caro teaches that the wavelength of the light incident on the patient's tissue is shifted in increments of 10 nm in the spectrum of wavelengths from 500 nm to 2500 nm. Caro does not teach

the use of a quantum cascade laser. The radiation source can be one or more diode lasers (column 11, lines 4-11 of Caro). Capasso discloses that quantum cascade (QC) lasers are used in medical diagnostic devices (column 1, lines 20-60 of Capasso) and they are suitable substitutes for diode lasers. The QC lasers can be tailored over a very wide wavelength range using the same semiconductor material. Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to substitute the QC lasers of Capasso for the diode lasers of Caro since the QC lasers can be tailored over a wide wavelength range using the same semiconductor material.

In regard to claim 2, the absorbed electromagnetic energy generates acoustic energy which is detected and analyzed to determine the presence and/or concentration of the chemical species in the matter. (Abstract of Caro). In regard to claim 3, a quantum cascade laser is used. (column 1, lines 20-60 of Capasso). In regard to claims 4-5, a plurality of light sources is used. (column 11, lines 4-11 of Caro). In regard to claims 6-7, a beam combiner (reference numerals 116 and 137 of Fig. 3 and reference numeral 111 of Fig. 1 of Caro) is disclosed. (column 11, lines 5-15 of Caro). In regard to claim 9, the same space is addressed. (Fig. 1 of Caro). In regard to claim 10, a pressure transducer 108 is disclosed. (Fig. 1 of Caro). In regard to claim 11, a coupling fluid is disclosed. (column 22, lines 13-16 of Caro). In regard to claims 12-14 and 24-25, the light sources are pulsed between 1 nanosecond to 1 millisecond (column 10, lines 14-18 of Caro) and the duty cycle is 50 Hz (column 12, lines 61-62 of Caro). In regard to claim 15, the pressure transducer has a spatial distribution. (column 20, lines

29-47 of Caro). In regard to claims 19-20, a data storage means is disclosed in computer 114. (column 13, lines 30-36 of Caro).

8. Claim 21 is rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent 5,348,002 to Caro in view of U.S. Patent 6,148,012 to Capasso et al. (Capasso) as applied to claim 1, and further in view of U.S. Patent 6,334,065 to Al-Ali et al. (Al-Ali). The combination does not teach the step of separately monitoring two locations. Al-Ali teaches that measuring at a plurality of locations at the same time is advantageous because it allows for cross-site comparisons. (column 3, lines 43-48 of Al-Ali). Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to take measurements at a plurality of locations at the same time as disclosed by Al-Ali since it is advantageous to perform cross-site comparisons. In regard to claim 21, measuring at two locations would require two measurement devices, which would mean there are two sets of lasers and acoustic detectors.

9. Claim 8 is rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent 5,348,002 to Caro in view of U.S. Patent 6,148,012 to Capasso et al. (Capasso) as applied to claim 6, and further in view of U.S. Patent 5,669,871 to Sakiyama. The combination teaches the use of a beam combiner in the form of optical fibers. (reference numerals 116 and 137 of Fig. 3 and reference numeral 111 of Fig. 1 of Caro). The combination does not teach the step of using prisms as part of the beam combiner. Sakiyama teaches that prisms are used for efficient coupling of light sources

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to optical fibers. (Fig. 27 and column 20, lines 1-8 of Sakiyama). Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to use the prism of Sakiyama in the combination since it will result in a more efficient coupling of light sources to optical fibers.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Matthew J Kremer whose telephone number is 571-272-4727. The examiner can normally be reached on Mon. through Fri. between 8:30 a.m. - 5:00 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max Hindenburg can be reached on 571-272-4726. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Matthew Kremer
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